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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,653	11/21/2003	Thomas P. Jerussi	4821-529-999	9144

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EXAMINER	
LEWIS, AMY A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,653	JERUSSI, THOMAS P.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *A-E*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Case

Claims 41-51, as filed on 21 November 2003 are presented for examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 41-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55-70 of copending Application No. 10/769860 (US Patent Application Pub. No. 2004/0162355 A1). Claims 55-70 of 10/769860 recite a method of treating a cerebral function disorder, which includes disturbance of consciousness and lowered attention, by administering a sibutramine metabolite, specifically (R)-desmethylsibutramine, (S)- desmethylsibutramine, (R)-didesmethylsibutramine, or (S)-

didesmethylsibutramine. The instant claims are directed to a method of treating narcolepsy by administering a sibutramine metabolite, specifically (S)- didesmethylsibutramine. Although the conflicting claims are not identical, they are not patentably distinct from each other because narcolepsy is a type of disturbance of consciousness and lowered attention. Therefore, the instant application is an obvious variation of claims 55-70 of copending Application No. 10/769860 (US Patent Application Pub. No. 2004/0162355 A1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2) Claims 41-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes the term "prodrug" to mean "a derivative of a compound that can hydrolyze, oxidize, or otherwise react under biological conditions (in vitro or in vivo) to provide the compound" (see specification p. 3). The specification also states that examples of prodrugs include derivatives of desmethylsibutramine and didesmethylsibutramine (p. 3). The

specification then goes on to state, "as used herein, prodrugs of didesmethylsibutramine and desmethylsibutramine do not include sibutramine (p. 4). The specification describes (S)-didesmethylsibutramine as a metabolite of sibutramine, which would make sibutramine a prodrug of (S)-didesmethylsibutramine. The specification disclosure as a whole only adequately describes sibutramine as a prodrug source.

The specification meets the written description and enablement requirements of 35 USC 112, first paragraph regarding sibutramine as a prodrug of desmethylsibutramine and didesmethylsibutramine requirements. However, the specification negates sibutramine as a prodrug of desmethylsibutramine and didesmethylsibutramine (p. 4, lines 1-2).

Claims 41-51 encompass any compound which is a prodrug of (S)-didesmethylsibutramine. The specification provides insufficient written description to support the genus (i.e. any prodrug) as encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of sibutramine, the skilled artisan cannot envision the detailed chemical structure of the encompassed possible prodrugs, regardless of the complexity or simplicity of related derivatives of the compound which may be prodrugs. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential variation or derivative of a compound. The specific compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that

> "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only sibutramine as a prodrug, but not the full breadth of the claim (any other (S)-didesmethylsibutrame prodrug) meets the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision.

3) Claims 41-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of narcolepsy with (S)-didesmethylsibutramine, does not reasonable provide enablement for prevention of narcolepsy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

> The term "prevention" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success. Since absolute success is not reasonably possible with most diseases, especially ones having etiologies as complex/poorly characterized as narcolepsy, the specification is viewed as lacking an adequate written description of same (indeed, it could not provide one).

The burden of enabling the prevention of a chronic condition such as narcolepsy (i.e. the need for additional testing) would be greater than that of enabling a treatment for narcolepsy. In the instant case, the specification does not provide guidance as to how one skilled in the art would go about preventing narcolepsy or how one could be kept from being susceptible to said ailment. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in preventing narcolepsy.

Specifically, it is highly unlikely, and the Office would require experimental evidence to a claim such as that of claims 41-51 which claims to absolutely prevent narcolepsy in a human by the simple administration of (S)-didesmethylsibutramine or prodrugs thereof to said human. The specification fails to enable one of ordinary skill in the art to practice and use the methods of instant claims 41-51.

Pertinent Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art of record does not support administration of (S)-didesmethylsibutramine to narcoleptic patients.

- Nishino S, et al., "Desmethyl metabolites of serotonergic uptake inhibitors are more potent for suppressing canine cataplexy that their parent compounds," 1993 *Sleep* 16(8): 706-712.
- Glick SD, et al., "Enantioselective behavioral effects of sibutramine metabolites,"

2000 *Euro J Pharm* 397: 93-102.

Conclusion

Claims 41-51 are rejected. No claims are allowed.

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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